

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION**

**MDL No. 1456
Master File No. 01-CV-12257-PBS**

THIS DOCUMENT RELATES TO:

Hon. Patti B. Saris

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil
Action No. 05-11084-PBS

**DEY DEFENDANTS' REPLY IN FURTHER SUPPORT OF
THEIR MOTION TO AMEND THE COURT'S JULY 17, 2007
MEMORANDUM AND ORDER TO INCLUDE A CERTIFICATION OF
AN IMMEDIATE APPEAL PURSUANT TO 28 U.S.C. § 1292(b)**

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I. PRELIMINARY STATEMENT

Defendants, Dey, Inc., Dey L.P., Inc., and Dey, L.P. (together, “Dey”), submit this reply memorandum of law in further support of their motion for an amendment of the Court’s July 17 Order to include the certification of an immediate appeal of the FCA Issues pursuant to 28 U.S.C. § 1292(b).¹ Certification of an immediate appeal is warranted here as each of the elements of section 1292(b) are met.

Nothing in the United States’ opposition (“U.S. Opp.”) calls for the denial of Dey’s motion. The FCA Issues are precisely the type of unsettled questions that are suitable for immediate appeal pursuant to section 1292(b). First, the United States does not dispute that the FCA Issues concern controlling questions of law which meet the first prong of the section 1292(b) standard. Second, the United States’ primary argument – that there is not a substantial ground for difference of opinion as to the FCA issues – is meritless. The FCA Issues are hotly contested and are not settled by any controlling First Circuit law. The Court’s July 17 Order itself highlights the contested nature of the FCA Issues in that it conflicts with the Second Circuit’s holding in *United States v. The Baylor University Medical Center*, 469 F.3d 263 (2d Cir. 2006) that an FCA action is commenced for statute of limitations purposes by the filing of the United States’ complaint-in-intervention and not by the filing of the relator’s complaint under seal. Finally, the United States’ argument that the FCA Issues should not be certified because they would not “dispose of this case” is wrong because it applies the wrong standard and conflicts with the numerous cases cited by Dey which have certified issues for appeal even though those issues would not have resolved the case.

¹ Except as otherwise defined herein, capitalized terms used in this reply memorandum shall have the meaning given them in the Dey Defendants’ Memorandum of Law In Support of Their Motion to Amend the Court’s July 17, 2007 Memorandum and Order to Include a Certification of an Immediate Appeal Pursuant to 28 U.S.C. § 1292(b) (“Dey Mem.”), dated July 31, 2007.

II. ARGUMENT

A. The FCA Issues Exemplify the Type of “Rare” Issues Which Are Properly Certified For An Immediate Appeal Pursuant to 28 U.S.C. § 1292(b)

In its opposition memorandum, the United States cites to three cases for the proposition that “the First Circuit has consistently hewed to a narrow interpretation of the statutory criteria.” (U.S. Opp. at 1.)² However, these cases actually stand for the proposition that, in cases which present novel and important issues, such as the FCA Issues, certification for an interlocutory appeal is entirely appropriate.

For example, in *In re San Juan Dupont Plaza Hotel Fire Litig.*, 859 F.2d at 1010 n.1, the First Circuit held: “[a]lthough the call is close, we believe the work product issue in this matter to be sufficiently novel and important, and the circumstances sufficiently out of the ordinary, as to fulfill the statutory requisites.” *See also Lane v. First Nat’l Bank of Boston*, 871 F.2d at 167 n.2 (holding “[o]nly rare cases will qualify for the statutory anodyne. This, we think, is such a case.”).

As in *In re San Juan* and *Lane*, the FCA Issues presented by the July 17 Order are “rare”, “novel” and “important” because no First Circuit decision has ever resolved them and the only Circuit Court that has decided one of the issues – the Second Circuit – reached a result contrary to that reached by this Court. As demonstrated in Dey’s moving memorandum, and further demonstrated below, the FCA Issues satisfy each of the three criteria set forth in section 1292(b) and certification is consistent with First Circuit precedent and the law that prevails across the country.

² The cases relied on by the United States are *Lane v. First Nat’l Bank of Boston*, 871 F.2d 166 (1st Cir. 1989); *In re San Juan Dupont Plaza Hotel Fire Litig.*, 859 F.2d 1007 (1st Cir. 1988); and *McGillicuddy v. Clements*, 746 F.2d 76 (1st Cir. 1984).

The United States quotes a portion of the decision in *McGillicuddy v. Clements*, 746 F.2d 76 (1st Cir. 1984), for the proposition that interlocutory appeals from a motion to dismiss are “particularly disfavored.” The United States is mistaken and, taken in context, the *McGillicuddy* decision actually supports Dey’s position here. Language from *McGillicuddy* that the United States overlooked makes it clear that it is not the nature of the motion from which the order originates that is important when deciding whether to certify an appeal under section 1292(b). Rather, the First Circuit held that it is the nature of the issue on which review is sought that is important:

We continue to adhere to the view that interlocutory certification under 28 U.S.C. § 1292(b) should be used sparingly and only in exceptional circumstances, and where the proposed intermediate appeal presents one or more difficult and pivotal questions of law not settled by controlling authority.

Id. at 76 n.1. Thus, under the *McGillicuddy* holding, certification is appropriate where, as here, “one or more difficult and pivotal questions of law not settled by controlling authority” are present, without regard to the procedural posture of the case.

That Dey’s interpretation of *McGillicuddy* is the correct one is demonstrated by the facts of that case. There, the appeal came before the First Circuit on a run of the mill pleading question. What is more, the question of law at issue – whether the plaintiff’s allegations stated a claim under 42 U.S.C. § 1983 – was resolved by a prior Supreme Court decision and several First Circuit decisions directly on point. *Id.* at 77-78. Thus, the question of law the First Circuit was asked to answer was not a “difficult and pivotal question[] of law not settled by controlling authority.” These facts demonstrate that while the First Circuit “would not normally allow an appeal from a denial of a motion to dismiss,” *id.* at 76 n.1, nothing in the *McGillicuddy* holding precludes the certification sought by Dey here because the FCA Issues are

difficult and pivotal questions of law distinct from the typical pleading questions normally at issue on a motion to dismiss.³

B. The FCA Issues Are Controlling Questions of Law

In its opposition, the United States does not dispute that the FCA Issues are controlling issues of law nor that they meet the first requirement under section 1292(b). (Dey Mem. at 4-5.) Nor could the United States dispute the controlling nature of the FCA Issues in light of the July 17 Order which noted the importance of the FCA Issues, holding that they are “critical” and “key” questions. (July 17 Order at 6, 12.)

C. There Is A Substantial Ground for Difference of Opinion

There is a substantial ground for difference of opinion regarding the FCA Issues which warrants immediate certification under 28 U.S.C. § 1292(b). A substantial ground for difference of opinion is present when there are “difficult and pivotal questions of law not settled by controlling authority.” *See Natale v. Pfizer Inc.*, 379 F. Supp. 2d 161, 181 (D. Mass. 2005) (internal quotations omitted), *aff’d*, 424 F.3d 43 (1st Cir. 2005); *see also Miara v. First Allmerica Fin. Life Ins. Co.*, 379 F. Supp. 2d 20, 68 (D. Mass. 2005) (certifying an “unsettled” question of law regarding preemption under ERISA for immediate appeal); *In re Mut. Life Ins. Co. of New York Premium Litig.*, 299 F. Supp. 2d 4, 8 (D. Mass. 2004) (finding a substantial ground for difference of opinion justifying certification based on a previous First Circuit decision).

Here, there is a substantial ground for difference of opinion as to whether the filing of a relator’s complaint commences an action under the False Claims Act because this

³ In addition, while the *McGillicuddy* court reversed the district court’s decision, it did so with instructions to dismiss the complaint without prejudice only. *Id.* at 78. Thus, the appeal did not definitively resolve any substantive issue. Here, by contrast, an appellate decision in Dey’s favor will forever terminate a portion of this case. *See* Point II.D, *infra*; *see also* Dey Mem. at 8-9.

issue is unsettled among district and circuit courts. The United States attempts to argue that this issue is settled, but concedes – as it must – that the Second Circuit’s opinion in *Baylor* conflicts with certain district court opinions. (U.S. Opp. at 3.) Sufficiently divergent opinions are present when courts of appeal and lower courts “have wrestled with the issue” and when, “[a]s might be expected, the results differ from case to case, as do the factual circumstances surrounding each decision.” *In re Hillsborough Holdings Corp.*, Case No. 94-439-CIV-T-25E, 1994 U.S. Dist. LEXIS 6472, 6-7 (M.D. Fla. April 25, 1994). Here, the United States cannot deny that there is a split between the district courts which have considered the FCA issues and the Second Circuit, and this split demonstrates that the law is not settled and that there is a substantial ground for difference of opinion which is sufficient to satisfy the second requirement of section 1292(b).

Moreover, neither the First Circuit, nor any district court in the First Circuit other than this Court has decided the issue. None of the district court cases cited by the United States are binding precedent in the District of Massachusetts or even the districts where those decisions were issued. *See Mills v. Apfel*, No. Civ. 99-27-P-H, 2000 WL 761796 (D. Me. Mar. 16, 2000) (holding that a matter was proper for appeal to the First Circuit, even though a district court in the same district decided the issue, because the First Circuit “has not yet taken a position on this issue that has divided the other Circuits.”); *see also In re Carrozzella & Richardson*, 255 B.R. 267, 272 (Bankr. D. Conn. 2000) (“It is widely accepted that the decision of one district court judge is not binding on another district judge, even within the same district.”)

There is also substantial ground for difference of opinion as to whether the United States’ complaint may relate back to the relator’s sealed complaint pursuant to Fed. R. Civ. P. 15(c)(1) for statute of limitations purposes. While this Court found that the U.S. Complaint relates back to Ven-A-Care’s Complaint filed in 1997, the issue is not resolved by any binding

precedent. Neither the United States nor the July 17 Order cites any binding precedent that has actually resolved this issue. A substantial ground for difference of opinion exists where, as here, “the court has not found any controlling authority directly addressing the issue.” *United States v. Moglia*, No. 02 C 6131, 2004 U.S. Dist. LEXIS 10424, 9-10 (N.D. Ill. June 7, 2004). Because “a definitive decision from the First Circuit [would] put to rest any confusion” regarding the FCA Issues which inhabit an unsettled and disputed area of law, certification for an immediate appeal under 28 U.S.C. § 1292(b) is warranted here. *Miara*, 379 F. Supp. 2d at 68.⁴

D. An Immediate Appeal Will Materially Advance the Ultimate Termination of this Litigation and Other Pending Claims

Finally, the United States argues that the resolution of Dey’s challenge to the July 17 Order will not materially advance the ultimate termination of the litigation. (U.S. Opp. at 6.) The crux of the United States’ position is that an appeal will not end this case nor the cases pending against Abbott Laboratories, Inc. (“Abbott”) and Roxane Laboratories, Inc. (“Roxane”). (*Id.* at 6-7.) The standard applied by the United States is incorrect, and the United States offers no legal support thereof. The United States also fails to address the cases cited by Dey which find that the resolution of issues certified on appeal need not dispose of the litigation.

Under section 1292(b), it is not essential that resolution of the questions of law at issue dispose of the entire case. Rather, all the Court must find is that the appeal will result in the material advancement of the ultimate termination of this litigation. Under section 1292(b), “[s]everal factors are pertinent in determining whether an immediate appeal would materially advance the ultimate termination of the litigation, including: (1) whether the need for trial would

⁴ Although the United States cites to the Supreme Court’s decision in *Rockwell International Corp. v. United States ex rel. Stone*, 127 S. Ct. 1397 (2007) in support of its relation back argument under Fed. R. Civ. P. 15(c)(1), the support that decision lends to the United States, if any, is merely by analogy. *Rockwell* is not on point and did not concern relation back in the FCA context. Thus, the issue of Fed. R. Civ. P. 15(c)(1) relation back presented here is one not resolved by binding authority and is ripe for determination by the First Circuit.

be eliminated; (2) whether the trial would be simplified by the elimination of complex issues; and (3) whether discovery could be conducted more expeditiously and at less expense to the parties.” *Patrick v. Dell Fin. Servs.*, 366 B.R. 378, 387 (Bankr. M.D. Pa. 2007) (internal citations omitted). Here, both the trial and discovery will be simplified and conducted more expeditiously and at less expense to the parties were Dey to prevail on its appeal. A decision in Dey’s favor will materially advance the termination of this action and others like it because it will partially dispose of, and greatly limit the scope of, the FCA claims against Dey, as well as the FCA claims against other defendants, such as Abbott and Roxane, which are currently facing similar claims in parallel cases.⁵ Furthermore, certification is particularly warranted because the FCA Issues have national importance. Courts across the country will be aided by an appellate determination that clarifies these issues.

In addition, certification is appropriate here because courts commonly certify questions for immediate appeal which do not involve ultimate, dispositive issues, such as questions pertaining to procedural issues, where, as here, the issues are unique and in dispute. For example, in *Bradburn Parent Teacher Store, Inc. v. 3M*, No. 02-7676, 2005 U.S. Dist. LEXIS 15815, at *9 (E.D. Pa. Aug. 2, 2005), the court stated that “courts should be mindful that resolution of the issue need not be determinative of any claim on the merits, and a possible reversal of the relevant order need not terminate the litigation.” In *In re San Juan*, the district

⁵ The United States argues – with no citation to authority – that even if Dey were to prevail on appeal, the scope of this action would remain the same because Ven-A-Care would be able to pursue the time barred claims the United States cannot. (U.S. Opp. at 6.) The United States is wrong. Once the DOJ intervened in the Ven-A-Care action pursuant to 31 U.S.C. § 3730(b)(2), Ven-A-Care ceased to “have a claim separate from the government’s. A qui tam relator has Article III standing to sue only as a relator, on behalf of the government. His standing is in the nature of an assignee of the government’s claim. Thus, there is one claim, the government’s, pursuable either by the qui tam relator on behalf of the government, or by the government on its own behalf.” See *United States ex rel. Barajas v. Northrop Corp.*, 147 F.3d 905, 910 (9th Cir. 1998) (internal citations omitted). Therefore, because there is only a single cause of action, if the Government’s claims are time barred, so too are the claims of Ven-A-Care.

court certified non-dispositive issues arising from a provision in a case management order. 859 F.2d at 1009. Similarly, in *Natale v. Pfizer Inc.*, 379 F. Supp. 2d at 182 (1st Cir. 2005), the district court certified an order involving a non-dispositive procedural issue regarding the commencement of actions under the Class Action Fairness Act. *Id.* at 182. *See also German v. Federal Home Loan Mortg. Corp.*, 93 Civ. 6941 (NRB), 2000 U.S. Dist. LEXIS 10057, at *5 (S.D.N.Y. July 20, 2000) (“Also, a reversal of our Order, while not necessarily terminating the litigation, would ‘effectively end plaintiffs’ federal claims,’ and would greatly simplify discovery and trial on the remaining claims if any.”). The FCA Issues, like the issues in the foregoing cases, are unique and in dispute as there exists no First Circuit precedent resolving them.

III. CONCLUSION

For the foregoing reasons, Dey respectfully requests that this Court amend its July 17 Order, pursuant to Fed. R. App. P. 5(a)(3), and certify it for immediate appeal, pursuant to 28 U.S.C. § 1292(b), and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: September 13, 2007

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on September 13, 2007, a copy to LexisNexis File & Serve for posting and notification to all parties.

_____/s/ Neil Merkl

Neil Merkl